#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

VALKIRS et al.

Title:

DIAGNOSTIC MARKERS OF

STROKE AND CEREBRAL INJURY AND METHODS OF

**USE THEREOF** 

Appl. No.:

10/714,078

Filing Date:

11/14/2003

Examiner:

Cook, Lisa V.

Art Unit:

1641

Confirmation

2621

Number:

# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Mail Stop Amendment-IDS Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR

§1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

### TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

## RELEVANCE OF EACH DOCUMENT

All of the documents are in English or have an English abstract.

Some of the documents being submitted were cited in a Supplementary European Search Report dated August 9, 2006 related to European Application 04760003.6-2404 and on a form PTO 892 by the Examiner assigned to U.S. Application No. 10/419,059 filed 4/17/03, U.S. Application No. 10/645,874 filed 8/20/03 and U.S. Application No. 10/673,077 filed 9/26/03. Other citations were cited in the International Search Report for International Application No. PCT/US05/32287 filed September 9, 2005.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

## **STATEMENT**

Fees in the amount of \$180.00 in accordance with 37 CFR §1.17(p) to cover the fee associated with an information disclosure statement under 37 CFR §1.97(c) are being paid by credit card via EFS-Web.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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	Substitute for for	rm 1449/	PTO	Complete if Known		
	INFORMATION D	DISCLO	SURE	Application Number	10/714,078	
STATEMENT BY APPLICANT				Filing Date	11/14/2003	<del></del>
				First Named Inventor	Gunars E. Valkirs	·····
				Art Unit	1641	
(use as many sheets as necessary)				Examiner Name	Cook, Lisa V.	***************************************
Sheet	1	of	2	Attorney Docket Number	071949-5408	

			U.S. PATENT DO	CUMENTS		
Examiner	Cite	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant	
Initials*	No. <sup>1</sup>	Number-Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear	
	A1	5,028,535	07/02/1991	Buechler et al.	1 iguico / ippear	
	A2	6,117,644	09/12/2000	Debold		
	A3	6,124,430	09/26/2000	Mischak et al.		
	A4	2004/0167341	08/2004	Haffner	****	

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Application Document Serial Number-Kind Code <sup>2</sup> (if known)	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
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			FOREIGN PATENT	DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	A5	WO 00/18801	04/16/2000	Ronn et al.		
	A6	WO 02/089657	11/14/2002	Biosite, Inc.		1
	Α7	WO 01/14885	03/01/2001	Biomedica Gesellschaft MBH		

		NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	tom (book magazina journal parial gymnasiyus asteles steel to the contract of			
	A8	Supplementary European Search Report - part of Communication dated August 9, 2006 for EP Application No. 04760003,6-2404.		
	A9	Allwords.com., Definition of "Appreciable"		
	A10	GREENBERG "Drug News and Perspectives", 1998, Vol. 11, No. 5, pp.265-70 (Abstract Only).		
	A11	HUNTER et al., "Analysis of Peptides Derived from Pro Atrial Natriuretic Peptide That Circulate in Man an Increase in Heart Disease", Scand J. Clin Lab Invest 56, 205-216 (1998)		
	A12	INDIK and ALPERT, Detection of pulmonary embolism by D-dimer assay, spiral computed tomography, and magnetic resonance imaging. Prog. Cardiovasc. Dis. 42:261-272, 2000		

Examiner	Date	
Signature	Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	Substitute for form	1449/F	OTO	Complete if Known		
	INFORMATION DIS	SCLO	SURE	Application Number	10/714,078	
	STATEMENT BY A	APPLIC	CANT	Filing Date	11/14/2003	
				First Named Inventor	Gunars E. Valkirs	
				Art Unit	1641	
	(use as many sheets	as nec	cessary)	Examiner Name	Cook, Lisa V.	
Sheet	2	of	2	Attorney Docket Number	071949-5408	

		NON PATENT LITERATURE DOCUMENTS	-
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	A13	MILLS et al., "Sustained Hemodynamic Effects of an Infusion of Nesiritide (Human b-Type Natriuretic Peptide) in Heart Failure", Journal of the American College of Cardiology, Vol. 34, No. 1, pp155-62 (1999)	
	A14	MULLINS et al., CT and conventional and diffusion-weighted MR imaging in acute stroke: Study in 691 patients at presentations to the emergency department. Radiology, 224(2): 353-360, 2002.	
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	A16	NG and ILAG, Biomedical applications of protein chips. J. Cell. Mol. Med., 6:329-340, 2002	
-	A17	"Tumor necrosis factor ligand superfamily member 12." Human Protein Reference Database, http://www.hprd.org/alternate?protein=04074&isoform_id=04074_1&isoform_name=Isoform_1	
	A18	VENUGOPAL, "Cardiac Natriuretic Peptides – Hope or Hype?", Journal of Clinical Pharmacy and therapeutics, Vol. 26, No. 1, 15-31 (2001)	
	A19	VESLEY et al., "Negative Feedback of Atrial Natriuretic Peptides", Journal of Clinical Endocrinology and Metabolism, Vol. 78, No. 5, 1128-1134 (1994)	
	A20	YIP et al., Time course and prognostic value of plasma levels of N-terminal pro-brain natriuretic peptide in patients after ischemic stroke. Circulation Journal, 70:447-452, 2006.	

Examiner	Date
Signature	Considered

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